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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,032	07/26/2001	Gregory M. Fahy	074066-0100	9126

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EXAMINER

WARE, DEBORAH K

ART UNIT PAPER NUMBER

1651

DATE MAILED: 09/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/916,032

Applicant(s)
Fahy

Examiner
Deborah Ware

Art Unit
1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.

- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.

- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Jun 20, 2002

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 19-45 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 19-45 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

4) ☐ Interview Summary (PTO-413) Paper No(s). _____

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) ☐ Notice of Informal Patent Application (PTO-152)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

6) ☐ Other:

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Claims 19-45 are pending.

The extension of time (3 months) and amendment of June 20, 2002 have been received and entered of record. However, upon reconsideration of the claimed subject matter and newly presented scope of the claimed methods a restriction requirement is deemed proper.

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 19-28 and 31-37, drawn to a method for reducing or eliminating cooling injury in a living system, classified in class 424, subclass 93.1.
 - II. Claims 29-30, drawn to a method for the rapid addition of at least one cryoprotective agent to a cell or tissue or organ, classified in class 435, subclass 325.
 - III. Claims 38-45, drawn to a method for reducing or preventing cooling injury in a living system, classified in class 514, subclass ~~14~~970.

2. The inventions are distinct, each from the other because of the following reasons:

Groups I-III are related to each other in that each are drawn to methods, however, each method is distinct one from the other since different process steps are required to carry out each of the claimed methods. The process steps of Group I do not require the process steps for rapid addition of at least one cryoprotective agent to its living system nor different temperature ranges for cooling as required of Group III. Although the addition of cryoprotectants are noted, the required steps for adding at least one cryoprotectant by rapid addition comprising in one step adding a second amount of the same cryoprotectant agent to produce a final amount of the agent,

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while increasing the concentration of the carrier solution to increase the tonicity of the preservation medium to a hypertonic state is different; and furthermore wherein the tonicity of the preservation medium is equal proportionally to an increase in the concentration of the same cryoprotective agent due to the second amount of the addition of the cryoprotective agent to the first amount. This is clearly a distinct process step of Group II and not required of Groups I and III.

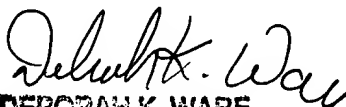
In the method of group 1 only one amount of the cryoprotective agent is added and the tonicity of the carrier solution is raised simultaneously with an increase in concentration of the cryoprotective agent from the addition of the first amount added for the claimed method for Group I. Overall the method steps and methods of Groups I and II and III are different one from the other and demonstrate two way distinctness so much that they are different processes. Also Group III is directed to the prevention not elimination of cooling injury and different process steps are required of the claimed method of Group III versus the Groups I and II. A first and second protective solution as is a first and second temperature range for actual cooling of the living system, are required of Group III. In addition, the protective solution is required to be prepared and is different from the cryoprotective agent of Groups I and II. Two way distinctness is apparent between each of the three groups I-III and each are different methods. Therefore, because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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3. A telephone call was made to Jay P. Hendrickson on September 24, 2002, to request an oral election to the above restriction requirement, but did not result in an election being made

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is (703) 308-4245.


DEBORAH K. WARE
PATENT EXAMINER

Deborah K. Ware

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September 30, 2002